UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,144	03/15/2001	Emilie Sparks	18633 . 00	3051

37833 7590 06/17/2005

LITMAN LAW OFFICES, LTD
PO BOX 15035
CRYSTAL CITY STATION
ARLINGTON, VA 22215

EXAMINER	
TOMASZEWSKI, MICHAEL	
ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/808,144	SPARKS, EMILIE	
	Examiner	Art Unit	
	Mike Tomaszewski	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *15 March 2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice To Applicant

1. This communication is in response to the application filed on 15 March 2001. Claims 1-20 are pending. The IDS statement filed on 15 March 2001 has been entered and considered.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 17, 18 and 20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The basis of this rejection is set forth in a two-prong test of:

(1) whether the invention is within the technological arts; and

(2) whether the invention produces a useful, concrete, and tangible result.

(A) For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena that do not apply, involve, use, or advance technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory subject matter. For a process claim to pass muster, the recited process must somehow apply, involve, use, or advance the technological arts.

In the present case, exemplary claim 17 is drawn to a multi-user distribution system for providing a patient with selective, diagnosis-related educational information and medical products, comprising the steps of selecting...; presenting...; distributing...; requesting...; and receiving. It is not clear whether or not the recited steps of inputting, correlating, delivering and selecting actively apply, involve, use, or advance the technological arts. In particular, these acts are capable of being performed in the human mind or via pencil and paper. As such, there is no specific requirement with the language of the claim to a practical application WITHIN the technological arts, as there is no requirement for any of the recited steps to be performed electronically or via computerized database components.

Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. In the present case, exemplary claim 1 is drawn to a multi-user distribution system for providing a patient with selective, diagnosis-related educational information and medical products, and as such, appears

to produce a useful, concrete, and tangible result, namely a system that provides a patient with pertinent healthcare information.

Although the recited process produces a useful, concrete, and tangible result, since the claimed invention, as a whole, is not within the technological arts as explained above, claim 1 is deemed to be directed to non-statutory subject matter.

(B) Claims 18 and 20 fail to further recite a positive and definite limitation to the technological arts, and also fail to pass muster under 35 U.S.C 101. The Examiner has noted insofar as claim 20 recites "at least one of printed, taped or electronic media," paper and pencil "media" are recited.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-2, 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Ilsen et al. (6,757,898; hereinafter Ilsen).

(A) As per claim 1, Ilsen discloses a multi-user distribution system for providing a patient with selective, diagnosis-related educational information and medical products (Ilsen; abstract), comprising:

(i) means for inputting a patient's request for material (Ilsen: col. 4, lines 65-67; col. 5, 1-3 and lines 23-43; Fig. 7);

(ii) means for correlating said request with at least one preselected material by diagnosis (Ilsen: col. 6, lines 21-32; col. 8, lines 37-41);

(iii) means for delivering at least one said material to said patient as a medical module (Ilsen: col. 6, lines 21-24; Fig. 3; Fig. 7) ((Note that examiner considers the various exemplary materials listed under Patient View on Fig. 3 (i.e., Medication Information, Personalized Health Topics, etc.) to be medical modules));

(iv) wherein said material(s) are selected from the group comprising educational products, medical assessment tests, and medical products (Ilsen: col. 4, lines 52-56; Fig. 3).

(B) As per claim 2, Ilsen discloses the multi-user distribution system for providing a patient with selective, diagnosis-related educational information and medical products of claim 1, further comprising a medical module and means for combining at least one said

material into a medical module to be sent to said patient (Ilsen: col. 6, lines 21-24; Fig. 3; Fig. 7).

(C) As per claim 17, Ilsen discloses a distribution method for providing a patient with a medical diagnosis with selective educational materials and medical products from healthcare experts (Ilsen: abstract) comprising the steps of:

(i) selecting a set of health-related materials (Ilsen: col. 6, lines 21-32; col. 8, lines 37-41);

(ii) presenting the patient to a subscriber of the medical subscriber system, wherein said presenting is one of direct and remote (Ilsen: col. 5, lines 24-26; col. 10, lines 30-32; Fig. 7);

(iii) distributing an education prescription to a patient (Ilsen: col. 6, lines 21-24; Fig. 3; Fig. 7);

(iv) requesting a medical module corresponding to a specific diagnosis of a patient's medical condition from said subscriber system (Ilsen: col. 4, lines 57-67; col. 5, 1-3 and lines 23-43; Fig. 7); and

(v) receiving a medical module from said subscriber system (Fig. 7).

(D) As per claim 18, Ilsen discloses the method of claim 17, further comprising the steps of extracting educational data from at least one database (Ilsen: col. 5, lines 28-30; Fig. 7).

(E) As per claim 19, Ilsen discloses the method of claim 17, wherein said modules provide at least one of: a prescription via online; Ilsen specifically discloses the use of online tools for prescription re-fills (Ilsen: col. 4, lines 52-56; Fig. 3).

(F) As per claim 20, Ilsen discloses the distribution method for providing at least one patient with a medical diagnosis according to claim 17, wherein said selecting step (i) further comprises the step of selecting educational material from at least one of printed, taped, or electronic media (Fig. 7: Ilsen discloses the selection of electronic media, taped, and/or printed media.); and, wherein said requesting step (iv) includes diagnosis medical conditions (Ilsen: col. 4, lines 57-63; col. 19, lines 41-45; Fig. 3).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 3-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ilsen as applied to claim 1 above, and further in view of Pauly et al. (4,958,280; hereinafter Pauly).

(A) As per claim 3, Ilsen fails to expressly disclose the multi-user distribution system for providing a patient with selective, diagnosis-related educational information and medical products of claim 2, wherein said means for delivering said medical module to a patient is carrier mail.

Nevertheless, the use of carrier mail as a means of delivery is old and well known in the art, as evidenced by Pauly et al. In particular, Pauly discloses a means of delivering medical products via carrier mail upon receipt of an order consummated remotely (e.g., an Internet order, telephone order, fax order, etc.) (Pauly: col. 3, lines 4-5; Fig. 1 and Fig. 2) Note that Examiner considers "shipped" to signify the use of traditional postal services (i.e., carrier mail).

It would have been obvious to one of ordinary skill in the art at the time of the invention to deliver said medical module to a patient via carrier mail with the motivation of providing effective delivery via cost-effective means (Pauly: col. 2, lines 30-33).

(B) As per claim 4, Ilsen discloses the multi-user distribution system for providing a patient with selective, diagnosis-related educational information and medical products of claim 3, wherein said means for receiving a patient's request for information is selected from the group comprising mail, fax, e-mail, online, networked systems, carrier, and telephone. In particular, Ilsen discloses the use of fax, email and networked online systems (Ilsen: col. 5, lines 10-12 and lines 24-42; Fig. 7).

(C) As per claim 5, Ilsen discloses the multi-user distribution system for providing a patient with selective, diagnosis-related educational information and medical products of claim 4, wherein said medical module is a self-learning module (Ilsen: col. 8, lines 37-47). Note that Examiner considers the patient's receipt of requested information to be a self-learning module because the impetus behind the patient requesting the information was to allow the patient to learn about their particular ailment.

(D) As per claim 6, Ilsen discloses the multi-user distribution system for providing a patient with selective, diagnosis-related educational information and medical products of claim 5, wherein said medical module comprises educational products which are diagnosis specific, said materials having been preselected and validated by at least one expert (Ilsen: col. 4, lines 57-65; col. 5, lines 10-12; Fig. 3). Note that Fig. 3 expressly discloses "post-visit instructions" (i.e., diagnosis specific educational products). Note also that the diagnosis-specific information is from the patient's own doctor and is therefore preselected and validated accordingly.

(E) As per claim 7, Ilsen discloses the multi-user distribution system for providing a patient with selective, diagnosis-related educational information and medical products of claim 6, wherein said medical module further comprises consumer medical assessment and monitoring products preselected by healthcare experts; said system further comprising means for receiving results from said medical assessment products for transmittal to a healthcare provider, and means for receiving data from said medical

products for conveying said data to a healthcare provider, said medical assessment products (Ilsen: col. 19, lines 29-37; Fig. 7).

(F) As per claim 8, Ilsen discloses the multi-user distribution system for providing a patient with selective, diagnosis-related educational information and medical products of claim 7, wherein said medical module further comprises health-related educational materials preselected by healthcare experts (Ilsen: col. 4, lines 57-65; col. 5, lines 10-12; Fig. 3) (Note that Examiner considers a doctor to be a healthcare expert.);

said system further comprising means for receiving responses to said educational modules, said responses being based on said patient's educative interaction with said modules (Ilsen: col. 4, lines 65-67; col. 5, lines 1-3 and lines 24-42; Fig. 7).

(G) As per claim 9, Ilsen discloses the multi-user distribution system for providing a patient with selective, diagnosis-related educational information and medical products of claim 8, wherein said health-related materials are up datable over time, said system further comprising means providing for updating said materials (Ilsen: col. 4, lines 52-65; col. 5, lines 56-57; Fig. 7).

(H) As per claim 10, Ilsen discloses the multi-user distribution system for providing a patient with selective, diagnosis-related educational information and medical products of claim 9, wherein said means for processing patient's information request further

comprises means for documenting the shipping-out of said health-related materials for said medical record (Ilsen: col. 5, lines 36-40; col. 8, lines 27-33).

(I) As per claim 11, Ilsen discloses the multi-user distribution system for providing a patient with selective, diagnosis-related educational information and medical products of claim 10, wherein a patient may present said patient's information request to said system in person or by any means other than in person (Ilsen: col. 5, lines 24-26; col. 10, lines 30-32; Fig. 7).

(J) As per claim 12, Ilsen discloses the multi-user distribution system for providing a patient with selective, diagnosis-related educational information and medical products of claim 11, wherein said system further comprises a database (Ilsen: col. 5, lines 28-30; Fig. 7).

(K) As per claim 13, Ilsen discloses the multi-user distribution system for providing a patient with selective, diagnosis-related educational information and medical products of claim 12, wherein said system further comprises medical devices and medical assessment tests, the results of which are subject to being remotely monitored by a physician (Ilsen: col. 19, lines 29-37; Fig. 7).

(L) As per claim 14, Ilsen discloses the multi-user distribution system for providing a patient with selective, diagnosis-related educational information and medical products of

claim 13, wherein said system automatically generates said module by electronic means upon diagnosis of said patient by a physician subscriber to said system (Ilsen: col. 4, lines 41-56).

(M) As per claim 15, Ilsen discloses the multi-user distribution system for providing a patient with selective, diagnosis-related educational information and medical products of claim 13, wherein said system is a subscription system, providing access thereto only through the direction of a physician subscriber to said system (Ilsen: col. 14, lines 66-67 and col. 15, lines 1-5; Fig. 3).

(N) As per claim 16, Ilsen discloses the multi-user distribution system for providing a user with selective, diagnosis-related educational information and medical products, comprising:

(i) means for inputting a user's request for a medical module (Ilsen: col. 4, lines 65-67; col. 5, 1-3 and lines 23-43; Fig. 7) correlated to said user's at least one diagnosis (Ilsen: col. 6, lines 21-32; col. 8, lines 37-41);

(ii) means for processing said user's at least one diagnosis with at least one set of expert selected materials (Ilsen: col. 6, lines 21-24; Fig. 3; Fig. 7);

(iii) means for combining at least one set of materials into a medical module to be sent to the user (Ilsen: col. 6, lines 21-24; Fig. 3; Fig. 7);

(iv) means for delivering said medical module to said user (Ilsen: col. 6, lines 21-24; Fig. 3; Fig. 7);

(v) wherein said module comprises materials selected from the group comprising consumer medical tests, medical devices, printed media, taped media, electronic media, filmed media, video, and CD-ROM (Ilsen: col. 4, lines 52-56; Fig. 7: Ilsen specifically discloses the selection of electronic media, taped, and/or printed media.);

(vii) wherein said system is capable of automatically generating said module by electronic means upon diagnosis of said patient by a physician subscriber to said system (Ilsen: col. 4, lines 41-56); and

(viii) wherein said system is at least one of a subscription system, providing access thereto only through the direction of a physician subscriber to said system (Ilsen: col. 14, lines 66-67 and col. 15, lines 1-5; Fig. 3).

Ilsen, however, fails to expressly disclose the multi-user distribution system for providing a patient with selective, diagnosis-related educational information and medical products, wherein said means for delivering said medical module to a patient is carrier mail.

Nevertheless, the use of carrier mail as a means of delivery is old and well known in the art, as evidenced by Pauly et al. In particular, Pauly discloses a means of delivering medical products via carrier mail upon receipt of an order consummated remotely (e.g., an Internet order, telephone order, fax order, etc.) (Pauly: col. 3, lines 4-5; Fig. 1 and Fig. 2) Note that Examiner considers "shipped" to signify the use of traditional postal services (i.e., carrier mail).

It would have been obvious to one of ordinary skill in the art at the time of the invention to deliver said medical module to a patient via carrier mail with the motivation of providing effective delivery via cost-effective means (Pauly: col. 2, lines 30-33).

Conclusion

1. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied art teaches a modular microprocessor-based health monitoring system (5,307,263); a home medical system and medical apparatus for use therewith (5,339,821); an expert system for providing interactive assistance in solving problems such as health care management (5,517,405); a prescription creation system (5,737,539); an apparatus and method for processing and/or for providing healthcare information and/or healthcare-related information (6,283,761); a method, apparatus and system for providing targeted information in relation to laboratory and other medical services (US2002/0007285); an in-waiting room health-care information service (US2002/0016967); a system for placing orders through the Internet to a selected store of a chain of stores whereby the order is delivered via carrier mail (US2002/0038261); a medical consultation management system (US2002/0152096); a method and apparatus for automated generation of a patient treatment plan (6,587,828); and an electronic healthcare information and delivery

management system with an integrated medical research architecture and capability (US2004/0260577).

The cited but not applied prior art also includes non-patent literature articles by PR Newswire (OCG Technology Introduces Your Own Health.com" Apr. 15, 1999. p. 1.); Nancy Ann Jeffrey (Health & Medicine (A Special Report): Doctors and Patients --- A Little Knowledge... Doctors are suddenly swamped with patients who think they know a lot more than they actually do" Oct. 19, 1998. Wall Street Journal. p.R.8.); and Hunter Whitney (Making Mouse Calls" Sep. 14, 1998. Brandweek. Vol. 39, Iss. 34. p.20.).

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Tomaszewski whose telephone number is (571)272-8117. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571)272-6776. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MT MT 6.13.05

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600